

DIVISION OF ENVIRONMENT
QUALITY MANAGEMENT PLAN

PART I:

DIVISIONAL QUALITY ASSURANCE MANAGEMENT
POLICIES AND PROCEDURES

Revision 1
October 30, 2004

Kansas Department of Health and Environment
Division of Environment
Curtis State Office Building
1000 SW Jackson, Suite 410
Topeka, Kansas 66612


Concurrences and Approvals

Concurrences, KDHE Division of Environment

Name: Clark Duffy
Title: Director, Bureau of Air and Radiation

Signature  Date 1-28-05

Name:
Title: Director, Bureau of Environmental Field Services

Signature  Date 1/28/05

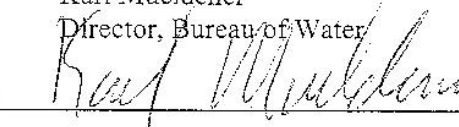
Name: Gary Blackburn
Title: Director, Bureau of Environmental Remediation

Signature  Date 1/19/05

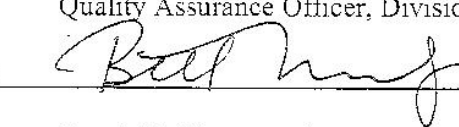
Name: William Bider
Title: Director, Bureau of Waste Management

Signature  Date 1-28-05

Name: Karl Muehdener
Title: Director, Bureau of Water

Signature  Date 1-31-05

Name: Bill Morris
Title: Quality Assurance Officer, Division of Environment

Signature  Date 1-19-05

Name: Ronald F. Hammerschmidt
Title: Director, Division of Environment

Signature  Date 1/28/05

Approvals, Kansas Department of Health and Environment

Name: Yvonne Anderson
Title: General Counsel, Kansas Department of Health and Environment

Signature Yvonne Anderson Date 2-8-05

Name: Roderick Bremby
Title: Secretary, Kansas Department of Health and Environment

Signature Roderick Bremby Date 2-11-05

Approvals, United States Environmental Protection Agency

Name: Diane Harris
Title: Regional Quality Assurance Manager, Region 7

Signature Diane Harris Date 04/27/2005

Name: James B. Gulliford
Title: Regional Administrator, Region 7

Signature James B. Gulliford Date 5/2/05

RECEIVED
2005047
FEB 23 2005

TABLE OF CONTENTS

<u>Section</u>		<u>Revision No.</u>	<u>Date</u>
1	INTRODUCTION		
1.1	Purpose of Document	1	10/30/04
1.2	Historical Background	1	10/30/04
1.3	Divisional Quality Assurance Goal	1	10/30/04
2	QUALITY ASSURANCE POLICIES		
2.1	Basic Principles	1	10/30/04
2.2	General Divisional Policies	1	10/30/04
2.3	Programs and Activities Subject to Policies	1	10/30/04
3	QUALITY ASSURANCE ORGANIZATION		
3.1	Structure of Division of Environment	1	10/30/04
3.2	Administrative Responsibilities	1	10/30/04
3.3	Role of Program/Project Managers	1	10/30/04
3.4	Staff Responsibilities	1	10/30/04
4	QUALITY SYSTEM DESCRIPTION		
4.1	Quality Management Plan		
4.1.1	Quality Assurance Program/Project Plans	1	10/30/04
4.1.2	Standard Operating Procedures	1	10/30/04
4.2	Management System Reviews	1	10/30/04
4.3	Program/Project Audits	1	10/30/04
4.4	Data Quality Assessments	1	10/30/04
4.5	Internal Program/Project Reviews	1	10/30/04
4.6	Staff/Supervisor Performance Evaluations	1	10/30/04
4.7	Annual Program/Project Evaluations	1	10/30/04
4.8	Annual Divisional Quality Assurance Report ...	1	10/30/04
5	PERSONNEL QUALIFICATIONS AND TRAINING		
5.1	Personnel Qualifications	1	10/30/04
5.2	Continuing Educational Opportunities	1	10/30/04
5.3	Quality Assurance Training	1	10/30/04
5.4	Supervisory Expectations	1	10/30/04
5.5	New Employee Orientation	1	10/30/04
5.6	Annual Review Affidavit	1	10/30/04
5.7	Safety Considerations	1	12/30/04

<u>Section</u>	<u>Revision No.</u>	<u>Date</u>
6	PROCUREMENT OF GOODS AND SERVICES	
6.1	Procurement of Services	1 10/30/04
6.2	Procurement of Equipment and Supplies	1 10/30/04
7	COMPUTER TECHNOLOGY	
7.1	Computer Hardware and Software	1 10/30/04
7.2	Data Entry Requirements	1 10/30/04
7.3	Verification of Calculations	1 10/30/04
8	DOCUMENTS AND RECORDS	1 10/30/04
9	PLANNING AND IMPLEMENTATION OF WORK	
9.1	Planning Requirements	1 10/30/04
9.2	Implementation Requirements	1 10/30/04
10	ASSESSMENT AND RESPONSE	
10.1	Assessments	1 10/30/04
10.2	Corrective Actions	1 10/30/04
11	QUALITY IMPROVEMENT	1 10/30/04
11.1	Quality Management Plan Review	1 10/30/04
11.2	Quality Assurance Communication	1 10/30/04
	APPENDIX A: GLOSSARY OF TERMS	1 10/30/04
	APPENDIX B: ADMINISTRATIVE AND QUALITY ASSURANCE STRUCTURE OF KDHE DIVISION OF ENVIRONMENT	1 10/30/04
	APPENDIX C: MAJOR FUNCTIONS OF BUREAUS AND OFFICES WITHIN KDHE DIVISION OF ENVIRONMENT	1 10/30/04

Section 1

INTRODUCTION

1.1 Purpose of Document

This quality management plan (QMP) describes the quality management system utilized by the Division of Environment (DOE), Kansas Department of Health and Environment (KDHE). Quality assurance goals, policies, procedures, organizational responsibilities, evaluation and reporting requirements, and other attributes of the DOE quality management system are addressed within this QMP. A glossary of technical terms used in this document is provided in Appendix A.

1.2 Historical Background

The Division's earliest efforts to develop a QMP began in 1983. These efforts led to the compilation of standard operating procedures for many of the Division's major environmental monitoring programs but did not explicitly address quality assurance objectives, policies, organizational responsibilities, and evaluation and reporting requirements. The original QMP was approved by the United States Environmental Protection Agency (EPA) on February 6, 1984 and served as the Division's principal quality assurance document for more than a decade.

During the 1980s, several DOE monitoring programs developed quality assurance plans independently of the Divisional QMP. Other DOE programs were implemented after the initial quality management initiative, and quality assurance plans for these programs were likewise formulated outside the framework of the original QMP. In 1995, these considerations led to a comprehensive revision of the QMP. The revised QMP was presented in three parts. Part I addressed quality assurance management policies and procedures required of all environmental monitoring programs and projects administered by (or on behalf of) DOE. Part II described additional policies and procedures administered by the individual bureaus and offices within DOE. Part III presented quality assurance plans and standard operating procedures for specific environmental monitoring programs/projects administered by the individual bureaus and offices. The revised QMP was approved by EPA on May 23, 1996, and another, minor revision of the QMP was approved by EPA on May 16, 1997. Federal review/approval in both instances was limited to Part I of the QMP.

The year 2000 version of the Divisional QMP retained the three-part composition originally adopted in 1995. However, Part I incorporated several new sections and other changes based on the federal guidance document, *EPA Requirements for Quality Management Plans* (EPA QA/R-2). Part II also had been updated to reflect recent organizational changes and the implementation of new duties within the Division's individual bureaus and offices. Finally, Part III had been revised to account for changes in environmental monitoring programs and projects administered by these bureaus and offices.

This current version of the Divisional QMP retains many of the previous versions attributes. There have been numerous minor changes to the document. The DOE was relocated in 2001 and all bureaus are together in one building. The EPA Region 7 QA Manager performed a Management

System Review (MSR) during the summer 2003, and several issues were identified as non-conforming to the 2000 approved DOE QMP. The DOE has implemented or changed text in this current version to reflect conformance on issues cited during the 2003 MSR.

1.3 Divisional Quality Assurance Goal

The foremost goal of the DOE quality management system is to ensure that all environmental monitoring operations administered by the Division produce data of known and acceptable quality and support, in a scientifically defensible manner, the informational needs and regulatory functions of KDHE.

Section 2

QUALITY ASSURANCE POLICIES

2.1 Basic Principles

Historically, the terms quality assurance (QA) and quality control (QC) were applied to manufacturing and corporate settings, where they referred to efforts to ensure the integrity of finished goods and services. These terms have gradually gained acceptance within environmental monitoring and research programs, wherein scientific databases and final program reports typically represent the major finished products.

The terms QA and QC are related but not synonymous. Quality assurance encompasses all measures taken by upper management to ensure that the quality of a finished product meets the standards of the company or organization. This includes measures to independently verify the claims of project managers and their staff. As applied to environmental monitoring programs, QA refers to the collective efforts of administrative staff to ensure that field and laboratory data meet the objectives of the organization and are acquired and utilized in an efficient and scientifically defensible manner. Major QA functions include review and approval of program planning documents, auditing of sample collection, sample analysis, and data handling procedures, and evaluating the effectiveness of implemented QC procedures.

Quality control encompasses all of the direct actions taken to achieve and maintain a desired level of quality for a given product. From an environmental monitoring perspective, QC includes all of the measures taken by project managers and field, laboratory and data management personnel to achieve a predetermined level of data reliability. Quality control is applied from the planning and design stages of the monitoring effort, through the implementation stages, to the handling, storage and reporting of accumulated data.

2.2 General Divisional Policies

The Division relies on environmental monitoring data to support a multitude of scientific, regulatory and administrative decisions. Accordingly, efforts to ensure, document and improve the quality of these data rank among the most important functions of staff. All monitoring activities performed within the Division (intramural activities) or conducted on behalf of DOE by independent contractors or consultants (extramural activities) are expected to comply fully with the following general policies:

- (1) The objectives of each environmental monitoring program or project shall be clearly delineated during the planning stages of the program/project. These objectives shall be consistent with the mission, policies and priorities of the Division.
- (2) Tolerable levels of data uncertainty shall be identified during the planning stages of each monitoring program/project so that appropriate procedures and resources may be incorporated into the design of the program/project.

- (3) Quality assurance and QC measures shall be integrated into all environmental monitoring programs/projects in the most cost-effective manner possible without hindering the attainment of the stated QA objectives.
- (4) A quality assurance project (program) plan (QAPP), describing how the activity will achieve the stated objectives and the required level of data reliability, shall be developed by the manager of each environmental monitoring program/project (see glossary). This document shall be reviewed and approved, at a minimum, by the supervising section chief or district environmental administrator (DEA) and by the bureau QA representative prior to initiation of data collection (section 4.1.1).
- (5) Sample collection, sample analysis, and data management activities shall be subjected to periodic evaluation by supervisory personnel and outside auditors to identify and correct deficiencies and enhance the credibility of each monitoring program/project.
- (6) Measures shall be instituted within each environmental monitoring program/project to ensure that the quality of obtained environmental data is accurately and permanently documented.

2.3 Programs and Activities Subject to Policies

The Division engages in a broad array of environmental monitoring operations (section 3.1). Data are routinely collected on the concentrations of physicochemical, radiological and microbiological contaminants in air, soil, water, fish tissue, and other environmental media. Additional information is obtained on contaminant levels in industrial air emissions, wastewater discharges, abandoned hazardous wastes, landfill materials, and mine spoils. At some ambient monitoring stations and remediation/reclamation sites, supporting data are gathered on prevailing biological, geological, hydrological and/or meteorological conditions. Information obtained through these efforts is used to identify and prioritize environmental problems, establish appropriate limits on the kinds and amounts of pollutants released into the environment, and monitor the effectiveness of pollution abatement and cleanup actions. Collectively, these monitoring efforts play a crucial role in protecting public health and the natural resources of Kansas.

The requirements of the QMP are applicable to all environmental monitoring and measurement operations performed, funded or required by the Division. This includes virtually all intramural and extramural environmental monitoring programs/projects. However, it is recognized that unusual or unprecedented situations may require immediate responses based on the best professional judgement of staff rather than the provisions of preexisting and approved QAPPs. To the extent practicable, such emergency responses should be based on established procedures.

Outside entities engaged in environmental monitoring operations under contractual agreement with the Division must develop QAPPs and SOPs compatible in coverage and form with sections 4.1.1 and 4.1.2 of this document. Alternatively, they must abide by QAPPs and SOPs developed by Divisional staff for the specific type of program/project of interest. All such QAPPs and SOPs, whether developed within or outside the Division, must be reviewed and approved by the

appropriate program/project manager, supervising section chief/DEA, and bureau QA representative. Environmental monitoring contracts awarded by DOE must contain provisions that ensure formal QAPPs are prepared and approved prior to the initiation of data collection. All QAPPs and SOPs associated with contractual monitoring operations must be maintained in an updated condition. Proposed changes in the work performed under a monitoring contract and associated QAPP must be reviewed and approved by the appropriate program/project manager, supervising section chief/DEA, and bureau QA representative prior to implementation.

Some regulated entities are required by the Division to monitor their contaminant releases into the environment. On occasion, these entities are required to perform more comprehensive pollutant transport, fate, and environmental impact studies. Bureaus requiring regulated entities to perform some level of environmental monitoring generally are expected to develop standardized QAPPs and SOPs compatible in coverage and form with the Divisional QA documentation. Alternatively, bureaus may direct regulated entities to develop QAPPs and SOPs and submit them to DOE for review and approval. All such documents, whether developed externally or by Divisional staff, must be approved by the appropriate program/project manager, supervising section chief/DEA and bureau QA representative prior to implementation. Facility-specific or site-specific sampling and analysis plans (SAPs) and similar documents used in some programs/projects (see Part II) are developed pursuant to approved QAPPs and SOPs and generally are reviewed and approved only by the responsible program/project manager.

Section 3

QUALITY ASSURANCE ORGANIZATION

3.1 Structure of Division of Environment

Environmental monitoring operations within KDHE are administered by DOE's Bureau of Air and Radiation, Bureau of Environmental Field Services, Bureau of Environmental Remediation, Bureau of Waste Management, and Bureau of Water. In addition, the Bureau of Water sponsors a variety of extramural monitoring projects. The regulatory, planning, and data gathering and analysis functions of these five bureaus are described in Part II of the QMP. An organizational chart illustrating the Division's current administrative and QA hierarchy is presented in Appendix B. Appendix C summarizes the primary responsibilities of the five bureaus.

3.2 Administrative Responsibilities

The phrase "administrative staff" in the following discussion refers to supervisory employees directly or indirectly responsible for one or more of the Division's environmental monitoring programs/projects and generally exercising some authority over at least one lower tier of supervisory staff. Included among the administrative staff are the Division Director, Divisional QA officer, bureau directors, bureau QA representatives, section chiefs, and DEAs. Each of these employees plays a designated role in the Divisional quality management system, as described below:

Division Director - This senior administrative official ultimately is accountable for the quality of all environmental monitoring operations performed by staff. Although day-to-day QA management is delegated to other supervisory employees within the Division, the Director is responsible for ensuring that QA is an identifiable feature of DOE environmental monitoring operations and that adequate resources exist to achieve the Divisional QA goal. The Director works closely with the agency secretary to ensure that the monitoring and QA goals of the Division are consistent with the mission and policies of the agency.

Divisional QA Officer - This individual reports directly to the Division Director on QA matters and serves as the principal QA liaison with EPA and other federal oversight agencies. He/she is primarily responsible for tracking changes in Divisional QA needs and federal QA requirements and for periodically reviewing and proposing necessary revisions to Part I of the QMP. The Divisional QA officer also ensures that independent QA reviews and audits are performed at an appropriate frequency, monitors the overall compliance of the Division with the provisions of the QMP, and annually compiles a Divisional QA performance report with assistance from the bureau QA representatives.

Bureau Directors - These supervisory personnel oversee the development, revision and implementation of the bureau QA management plans (Part II of QMP). With the assistance of the bureau QA representatives and section chiefs/DEAs, they ensure that the requirements of these management plans are fulfilled in the most cost effective manner possible without hindering attainment of the stated QA objectives. Bureau Directors prioritize the training

and continuing educational needs of staff and develop funding proposals to accommodate these needs, as necessary.

Bureau QA Representatives - These employees are directly responsible for reviewing and approving QAPPs and SOPs administered by their respective bureaus. They also provide guidance to program/project managers involved in the preparation and implementation of these documents. Within their respective bureaus, they operate under a degree of autonomy which allows them to make independent assessments of QA performance and the need for corrective action. The bureau QA representatives analyze QA evaluation reports and related information submitted by section chiefs/DEAs and program/project managers. They work with these supervisory staff and the Divisional QA officer in the resolution of identified QA problems and concerns.

Section Chiefs and DEAs - These employees generally are responsible for more than one environmental monitoring program/project and may supervise other, front line supervisors such as program/project managers. They oversee the QA aspects of environmental monitoring programs/projects on an ongoing basis, identify QC deficiencies within their respective programs/projects, track the QC performance of staff, and participate in the periodic review and revision of bureau QA management plans (Part II of QMP) and associated QAPPs and SOPs (Part III of QMP). Section chiefs/DEAs coordinate closely with program/project managers to ensure that all applicable QA and QC requirements are routinely and correctly implemented.

3.3 Role of Program/Project Managers

Managers of environmental monitoring programs/projects work closely with nonsupervisory staff to ensure that all QAPP and SOP requirements are implemented in a timely, consistent and technically appropriate fashion. Together with the section chiefs and DEAs, these managers strive to improve the efficiency of environmental monitoring operations through the prudent, day-to-day allocation of staff and other resources. They also bring the QC training needs of staff to the attention of their section chiefs/DEAs, develop QAPPs and SOPs for new monitoring initiatives, and periodically review and revise existing QAPPs and SOPs to meet the evolving informational needs of the Division.

3.4 Staff Responsibilities

Nonsupervisory staff involved in the collection and analysis of environmental monitoring data play an important role in the implementation of the QMP. To a large extent, the quality and usefulness of the environmental data collected by the Division reflect the willingness of these staff to abide by approved QAPPs and SOPs and to participate constructively in the ongoing review and revision of these documents. Because they carry out the provisions of these plans and procedures on a routine basis, nonsupervisory staff often develop a keen understanding of the technical strengths and weaknesses of the Division's environmental monitoring operations. Program/project managers and other supervisors are expected to solicit input from nonsupervisory staff when developing new or revised QAPPs and SOPs.

Section 4

QUALITY SYSTEM DESCRIPTION

The DOE quality management system for environmental monitoring operations centers around parts I, II and III of the QMP and the following related actions: management system reviews, program/project audits, data quality assessments, internal program/project reviews, staff/supervisor performance evaluations, and annual program/project evaluations. The following discussion considers the major elements of the QMP and each of these referenced actions, in turn.

4.1 Quality Management Plan

Part I of the QMP establishes the overarching framework for the Divisional quality management system. It is subject to ongoing review and revision according to the schedule established in section 11, below. Although primary responsibility for updating Part I of the QMP rests with the Divisional QA officer, input from bureau QA representatives and other administrative staff is considered an integral aspect of this process. Minor revisions to Part I of the QMP are subject to the review and approval of the Divisional QA officer and Division Director. Major revisions, reflecting significant changes in the Divisional quality management system, require the approval of the Divisional QA officer, Division Director, KDHE general counsel, KDHE Secretary, EPA regional QA manager, and EPA regional administrator. Changes constituting major revisions are identified by the Divisional QA officer in consultation with the Division Director and EPA regional QA manager.

Part II of the QMP contains the bureau QA management plans. These present a more detailed set of QA expectations tailored to the needs of the individual bureaus and offices but compatible in general form and content with Part I of the QMP. Each bureau QA management plan states the mission and developmental history of the bureau quality management system and sets forth detailed QA goals, policies, procedures, organizational responsibilities, evaluation and reporting requirements and other technical requirements. Each plan is reviewed at least annually and updated, if needed, by the bureau QA representative (section 11). Minor revisions to Part II of the QMP are reviewed and approved by the appropriate bureau QA representative and bureau director. Major revisions, reflecting significant changes in the bureau quality management system, are reviewed and approved by the bureau QA representative, bureau director, Divisional QA officer, and Division Director. Changes constituting major revisions are identified by the bureau QA representative in consultation with the Divisional QA officer. Deviations in Part II of the QMP from the overarching Divisional policies set forth in Part I of the QMP are approved only under exceptional circumstances and must be clearly explained and justified within the bureau QA management plan.

Part III of the QMP contains QAPPs and SOPs utilized by the individual environmental monitoring programs/projects. Owing to their prominent role in the Divisional quality management system, QAPPs and SOPs are given special mention in the following paragraphs.

4.1.1 Quality Assurance Program/Project Plans

A QAPP must be developed for each environmental monitoring program/project by the responsible program/project manager and approved by the supervising section chief/DEA and appropriate bureau QA representative prior to the initiation of data collection. Quality assurance program/project plans implementing 40 CFR 58, appendix A, and 40 CFR 35, subpart O, must also be reviewed and approved by the divisional QA officer and EPA regional QA manager. KDHE has been granted the authority, by EPA Region 7, to review and approve submitted QAPP's for Brownsfield, Pre-remedial and Federal sites. Brownsfield sites are operated under STAG grants and are not subject to 40 CFR Part 35, Subpart O. KDHE has obtained approval to review and approve QAPPs for non-state EPA grantees. Pre-remedial and Federal sites utilize EPA approved generic QAPPs supported by site specific addenda. Any proposed QAPP which does not meet applicable state or federal requirements, including the requirements contained in this section, must be returned to the program/project manager for further revision, then resubmitted for final approval. If the QAPP originates from a source outside the division and does not meet minimum requirements, it must be returned through the program/project manager to the outside source for revision, then resubmitted to DOE for final approval. For unusual or unprecedented monitoring operations unrelated to 40 CFR 58, appendix A, and 40 CFR 35, subpart O, the bureau QA representative may request an additional tier of review/approval by the divisional QA officer. At the discretion of the divisional QA officer, and with the concurrence of the division director, such QAPPs may be submitted to the EPA regional QA manager for federal review and approval.

Each QAPP must be prepared using a standardized document control format in which the report identity, revision number, date of revision, section number, and page number appear in the upper right-hand corner of each page. Each QAPP must contain the following informational elements unless the reviewing bureau QA representative determines that a given element falls outside the technical scope of the program/project:

- (1) title page identifying program/project, bureau, Division and agency;
- (2) approval page with blocks for appropriate signatures and dates;
- (3) table of contents, including a list of any appendices;
- (4) overview of program/project, including statement of purpose, developmental history, and any relevant statutory and regulatory requirements;
- (5) description (or chart) of organizational hierarchy with accompanying list of participating staff positions and statement of staff responsibilities;
- (6) description of data performance criteria expressed in terms of data precision, accuracy, completeness, comparability and representativeness for each parameter of interest;
- (7) description of, and rationale for, intended sampling frequency, sampling network design and monitoring site selection criteria;

- (8) description of sampling equipment and associated decontamination procedures (reference SOPs, as appropriate);
- (9) description of field procedures, including sample collection, analysis, preservation, transport and chain-of-custody procedures and accompanying safety protocols (reference SOPs, as appropriate);
- (10) list of laboratory parameters and sample holding times and accompanying description of laboratory analytical and safety protocols (note: SOPs adopted by the Kansas Division of Laboratories or other cooperating laboratories may be adopted by reference, provided they contain the informational elements stipulated in section 4.1.2, below);
- (11) description of data validation, storage, transfer, reporting and backup requirements and any special documentation requirements (reference SOPs, as appropriate);
- (12) description of equipment testing, calibration and preventative maintenance procedures (reference SOPs, as appropriate);
- (13) description of inspection procedures and acceptance requirements for purchased equipment and supplies (reference SOPs, as appropriate);
- (14) description of procedures (including statistical procedures) used to evaluate data precision, accuracy, completeness, representativeness and comparability, including a detailed characterization of internal QC procedures and external performance audit requirements;
- (15) description of procedures used to evaluate and enhance utility of environmental monitoring data including, but not necessarily limited to, procedures and assumptions applied in the identification and treatment of (a) outliers and other anomalous data, (b) nonlinear data requiring statistical transformation, and (c) values reported as “less than” or “greater than” established reporting limits;
- (16) description of corrective action procedures for out-of-control situations;
- (17) description of procedures for determining the quality of ancillary data acquired from external sources not subject to the provisions of the Divisional QMP (e.g., meteorological, hydrological, geological, chemical and/or biological data obtained from other state and federal agencies); and
- (18) description of program/project deliverables (electronic databases, summary statistics, illustrative materials, interim and final reports, etc.) and schedule for completion.

Additional points to consider when preparing a QAPP are presented in the EPA documents *Guidance for Quality Assurance Project Plans* (EPA QA/G-5) and *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5).

4.1.2 Standard Operating Procedures

Standard operating procedures document protocols used in the collection, preservation, transport, transfer and analysis of environmental samples and in the collection, validation, storage, retrieval, transfer, backup and analysis of environmental data. As such, they facilitate consistency among staff, serve as valuable references and training tools, and provide formal written records of the methods used to implement environmental monitoring operations. All SOPs must be scientifically rigorous and compatible with the data performance criteria set forth in their respective QAPPs.

Standard operating procedures are developed by the responsible program/project manager and reviewed and approved by the supervising section chief/DEA and bureau QA representative. Proposed SOPs which do not meet with the approval of the section chief/DEA or bureau QA representative are returned to the program/project manager for further revision, then resubmitted for final approval. If an SOP originates from a contractual source and does not meet with the approval of the program/project manager, section chief/DEA or bureau QA representative, it must be returned to the originating source for revision and resubmitted to DOE for final approval.

Approved SOPs may be appended to the end of a QAPP or adopted by reference within the text of a QAPP. SOPs originating within DOE should employ a standardized document control format in which the report identity, section number, revision number, date of revision, and page number appear in the upper right-hand corner of each page. Elements to consider when preparing an administrative, field, or laboratory SOP are presented in the EPA document *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents* (EPA QA/G-6). In general, technical SOPs involving field work and related sample and data collection activities should contain the following informational elements, unless the reviewing bureau QA representative determines that a given element or combination of elements falls outside the technical scope of the environmental monitoring program/project:

- (1) title page with appropriate blocks for approval signatures/dates;
- (2) table of contents including a list of any appendices;
- (3) introductory statement describing intended application of SOP and providing overview of procedure;
- (4) statement of minimal technical qualifications for participating staff;
- (5) instructions for calibrating field instruments and performing associated troubleshooting procedures;
- (6) instructions for collecting, preserving and handling environmental samples and/or performing environmental measurements, emphasizing health and safety considerations and highlighting any steps requiring special attention, patience or care;

- (7) instructions for collecting and analyzing duplicate or replicate samples and for preparing field blanks, spikes and split samples, emphasizing health and safety considerations and highlighting any steps requiring special attention, patience or care;
- (8) instructions for preparing and analyzing samples in the field and performing related troubleshooting procedures, emphasizing health and safety considerations, steps requiring special attention, patience or care, and possible interferences jeopardizing data quality;
- (9) instructions for transporting, transferring and storing environmental samples and accompanying field data and records (e.g., notes, logs, photographs, audio tapes, audiovisual tapes), emphasizing chain-of-custody procedures, health and safety considerations, and steps requiring special attention, patience or care;
- (10) description of data acquisition, storage, retrieval, transfer, verification, backup and analysis procedures, long-term data/records management procedures, and enabling computer hardware and software;
- (11) glossary of technical terms and acronyms employed in SOP (often included as appendix); and
- (12) checklist of applicable field equipment and supplies (often included as appendix).

4.2 Management System Reviews

A management system review (MSR) is a formal assessment of an organization's quality management system, examining whether the QA policies and procedures being implemented by the organization are consistent with the stated requirements of the organization. As part of the DOE quality management system, MSRs may be conducted for each bureau by the Divisional QA officer. Auditors from EPA may perform MSRs for the entire Division at the discretion of the EPA regional QA manager. The scheduling of these federal and internal MSRs is determined with input from the bureau QA representatives, the bureau directors, and the Division Director. Management system reviews conducted by the Divisional QA officer and by EPA normally follow the guidelines set forth in the EPA document *Guidance for Preparing, Conducting and Reporting the Results of Management System Reviews* (EPA QA/G-3, draft 1993). Internal and external MSRs help to identify needed corrective actions and opportunities for improving QA performance. The results of these assessments are summarized in writing and distributed to the bureau QA representatives, bureau directors, and the Division Director.

4.3 Program/Project Audits

Individual monitoring programs/projects may be audited by the Divisional QA officer, bureau QA representative, federal oversight agency, or an independent third party contracted by the Division or oversight agency. Most internal audits are performed by the bureau QA representatives based on perceived need or according to schedules set forth in the bureau QA management plans (Part II of

QMP). From time to time, the Divisional QA officer may plan, perform or oversee an auditing operation provided (a) the operation has been approved by the Division Director and (b) the bureau QA representative and bureau director have been informed of the operation. Internal audits may consider the adequacy of physical facilities, equipment, personnel, training, field and laboratory procedures, record keeping, data validation and management, and other aspects of the targeted monitoring programs/projects. The EPA document *Guidance on Technical Audits and Related Assessments for Environmental Data Operations* (EPA QA/G-7) serves as the principal written guidance for planning and conducting internal audits. Audit findings are shared with section chiefs/DEAs, program/project managers and other participating staff. Corrective actions stemming from audits, and approved and implemented pursuant to section 10.2, below, are addressed by the section chiefs/DEAs in annual program/project evaluation reports (section 4.7).

4.4 Data Quality Assessments

Data quality assessments are statistical evaluations which determine whether the type, quantity and quality of environmental data collected by a monitoring program/project support the informational needs of the administering bureau and the Division. These assessments focus largely on sampling design and monitoring frequency and the general adequacy of the collected data relative to the stated purpose of the monitoring effort. The EPA document *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* (EPA QA/G-9) serves as the principle written guidance for Divisional data quality assessments. Such assessments are performed by the bureau QA representatives or section chiefs/DEAs based on perceived need or according to schedules set forth in the bureau QA management plans (Part II of QMP). The results of data quality assessments are conveyed to all program/project participants. Corrective actions stemming from these assessments are addressed by section chiefs/DEAs in the end-of-year program/project evaluation reports (section 4.7).

4.5 Internal Program/Project Reviews

Quality control aspects of routine environmental monitoring operations are subject to ongoing review by the responsible program/project managers and section chiefs/DEAs. Program/project managers are expected to cooperate fully with administrative requests for information on data precision and accuracy and overall QC performance. Section chiefs/DEAs are expected to track the QC and supervisory performance of program/project managers, assist these managers in identifying QC deficiencies within their respective programs/projects, and facilitate necessary corrective actions. Results of internal reviews conducted by section chiefs/DEAs are summarized in the annual program/project evaluation reports (section 4.7).

4.6 Staff/Supervisor Performance Evaluations

Position descriptions and performance evaluations shall reflect the QA and QC functions and performances of staff. All staff involved in environmental monitoring operations are expected to carry out their responsibilities under the QMP to the best of their abilities. Administrative staff and program/project managers are expected to foster an appreciation for the role of QA and QC among nonsupervisory employees. In turn, the QA and QC opinions and insights of nonsupervisory employees shall be carefully considered by program/project managers and administrative staff. The

quality and credibility of the Division's environmental monitoring efforts ultimately depend on the willingness of all employees to work as a team, learn from their mistakes, and continually strive for improvement.

4.7 Annual Program/Project Evaluations

End-of-year program/project evaluations shall be conducted by section chiefs/DEAs and the results submitted, in writing, through the appropriate bureau QA representative to the bureau director and Divisional QA officer by February 15 of the following year. These written evaluations shall indicate when, how, and by whom the evaluation was conducted and describe the specific aspects of the programs/projects subjected to review. They shall include a summary of important findings and recommendations for any necessary corrective actions. Section chiefs/DEAs shall discuss the findings of these evaluations with program/project managers and participating field, laboratory, and data management staff.

4.8 Annual Divisional Quality Assurance Report

By March 15 of each year, the Divisional QA officer shall prepare a written report which summarizes the QA performance of the Division during the preceding calendar year and presents recommendations for improving the Divisional quality management system. This report shall be submitted to the Division Director for review and approval. Upon approval by the Division Director, a copy of the report shall be submitted by the Divisional QA officer to the EPA regional QA manager for informational purposes only.

Section 5

PERSONNEL QUALIFICATIONS AND TRAINING

5.1 Personnel Qualifications

All Divisional employees involved in the collection, handling and analysis of environmental samples or in the collection, storage, retrieval, transfer and examination of environmental data must possess the minimum level of education, training and experience necessary to meet the demands of their position (as reflected in the class specifications for the job position or in the employee position description). The knowledge and skills possessed by staff and supervisory personnel strongly influence the quality of environmental monitoring data, the interpretation of these data, and the appropriateness of most administrative and regulatory actions taken by the agency.

5.2 Continuing Educational Opportunities

Methods employed in the collection and analysis of environmental samples and environmental data are subject to continual review and improvement. Occasional conceptual or technological breakthroughs may rapidly antique existing procedures and protocols and require extensive training or retraining on the part of staff. Continuing educational courses offered by some colleges or vocational educational institutions may fulfill these training needs. Staff participating in such courses may be reimbursed by the Division provided the course subject matter is within the general scope of the employee position description, funds for training have been set aside within the budget of the beneficiary program/project, requests for reimbursement have been approved prior to attending training, and participation is otherwise allowable under prevailing agency training and travel policies.

5.3 Quality Assurance Training

Bureau QA representatives are responsible for working with section chiefs/DEAs and program/project managers to ensure that all staff implementing QAPPs and SOPs are familiar with their responsibilities under the QMP and have received an appropriate level of QA training. As training opportunities and agency resources allow, section chiefs/DEAs and program/project managers are expected to complete the following (or equivalent) EPA training courses: *Orientation to Quality Assurance*, *Systematic Planning Process (Data Quality Objectives)*, *Quality Assurance Project Plans*, and *Standard Operating Procedures*. The Divisional QA officer and bureau QA representatives are similarly expected to complete the above-mentioned courses and the following (or equivalent) EPA courses: *Quality Management Plans* and *Data Quality Assessments*. As resources and work priorities allow, other employees shall be encouraged to participate in QA training courses offered by EPA. Quality assurance training needs shall be addressed by section chiefs/DEAs in the end-of-year program/project evaluation reports discussed in section 4.7, above.

5.4 Supervisory Expectations

The quality of the Division's environmental monitoring data is strongly influenced by the level of staff training, experience and preparation. Section chiefs/DEAs are expected to address the general training needs of staff within the annual program/project evaluation reports. This information is incorporated annually into the DOE budget prepared by fiscal staff, the bureau directors and the Division Director. To broaden the experience of staff, supervisors may provide occasional opportunities for interested employees to participate in activities outside their daily work routines (i.e., interprogram cross-training opportunities). Such activities must be within the general scope of the employee classification specifications and conform to the training requirements presented in sections 5.5 and 5.7, below.

5.5 New Employee Orientation

Supervisors shall ensure that new employees (including newly hired employees and recent transfers or cross trainees from other programs/projects) receive a thorough indoctrination into the QA and QC policies and procedures of the Division and the applicable bureau and program/project. This document (Part I of QMP), and applicable bureau QA management plans, QAPPs and SOPs, shall be required reading on the part of new employees. Apart from QA and QC considerations, supervisors shall ensure that new employees participate in orientation and training seminars required by the KDHE Office of Human Resources Management. Similarly, new supervisory employees are expected to successfully complete the introductory training course for supervisors offered by the Department of Administration. New employees must demonstrate a satisfactory understanding of safety considerations before they are permitted by their supervisors to participate independently in any potentially hazardous activity (section 5.7).

5.6 Annual Review Affidavit

All DOE employees participating in environmental monitoring activities shall review Part I of the QMP and applicable portions of parts II and III of the QMP at least once each year. Upon completion of this review, each employee shall sign an affidavit indicating he/she has read the appropriate QA documentation. The signed affidavit shall be routed through the immediate supervisor and bureau QA representative to the Divisional QA officer. This review requirement shall be incorporated into the employee's written job expectations and factored by the immediate supervisor into the employee's annual performance evaluation.

5.7 Safety Considerations

Field staff participating in monitoring programs/projects encounter potentially hazardous situations on a frequent basis. To minimize this risk, field staff(at the discretion of the supervisor) shall complete 40 hour basic HAZWOPER training and must observe all safety requirements set forth in the Interim Division of Environment Safety Policy and subsequent Divisional safety policies.

Section 6

PROCUREMENT OF GOODS AND SERVICES

6.1 Procurement of Services

Contractual services involving the acquisition or analysis of environmental data shall be planned and controlled to ensure that these services meet applicable technical and QA requirements. All contracts for services shall require a QAPP to be developed by the outside contractor and submitted to DOE for review and approval prior to the initiation of data collection (section 4.1.1). Procurement of services shall comply with procedures described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Contracts shall reference or contain specific drawings, regulatory requirements, specifications, codes, standards, standard methods, procedures and/or instructions that describe the services to be provided by the contractor. Contracts also shall specify minimal requirements for evaluating the suitability and acceptability of any data, reports or other deliverables stemming from the contractual agreement. Program/project managers shall be directly responsible for ensuring that deliverables meet the requirements stipulated in the contracts. Section chiefs/DEAs and bureau QA representatives are expected to assist program/project managers in resolving any questions relating to the QA and QC aspects of contractual services.

6.2 Procurement of Equipment and Supplies

The procurement of equipment and supplies (goods) for environmental monitoring operations shall be planned and controlled to ensure that the quality of obtained goods is documented and meets the technical requirements of DOE. Procurement of goods shall in all instances abide by the procedures described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Quality assurance specifications shall be clearly indicated in purchase orders or related procurement documents. As needed to comply with data performance criteria, reference shall be made in the procurement documents to specific regulatory requirements, specifications, codes, standards, methods, procedures, or instructions. The procurement documents shall specify minimal technical requirements for acceptance of goods by DOE. Certificates of conformance shall accompany the delivery of chemical reference standards, calibration gases, calibration and reference equipment, and similar goods. Program/project managers (or their designees) shall ensure that all technical specifications are met before goods are accepted by DOE. Section chiefs/DEAs and bureau QA representatives shall assist in these activities, as needed. This requirement does not apply to services, equipment and supplies purchased under statewide contracts developed by the Division of Purchases, Department of Administration, on behalf of state agencies.

Section 7

COMPUTER TECHNOLOGY

7.1 Computer Hardware and Software

All purchases of computer hardware and software must be approved in advance by the KDHE Office of Information Systems (OIS) and abide by the purchasing requirements described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Anti-virus software approved by OIS shall be installed and utilized on all DOE lap-top and desktop computers, minicomputers and mainframe systems used for storage, retrieval, exchange, backup and/or analysis of environmental data.

7.2 Data Entry Requirements

Environmental data (and metadata) manually entered into a state or federal computer database by any DOE employee shall be examined and verified by at least one other DOE employee familiar with the database. This process shall entail the selection of a representative, randomly selected sample of data and the documentation and correction of any data entry errors. The percentage of data subjected to review, the method of review, and the reviewer shall be specified in the approved QAPP. Staff transferring data electronically shall perform random spot checks of the transferred data and report any problems to OIS (or the external cooperating entity) for further investigation and resolution. Persistent or recurring problems also shall be reported to appropriate supervisory staff and the bureau QA representative for determination of necessary corrective actions. Such problems shall be addressed in the end-of-year program/project evaluation reports (section 4.7).

7.3 Verification of Calculations

Computer-based mathematical, statistical, geographical and graphical programs and models involving environmental data shall be tested before application and periodically thereafter. The reliability of software for performing calculations shall be tested by comparison to other computer programs, through hand calculations involving randomly selected data, or through other appropriate means. The reliability of computer-based calculations shall be verified according to schedules established in applicable QAPPs and whenever a problem is reported within the computational system. Quality assurance program/project plans shall describe the types of computer-based calculations to be performed and prescribe measures for monitoring the precision and accuracy of these calculations. This requirement may be waived in writing by the bureau director for specific applications involving commercial software after review by the bureau director and bureau QA representative. Originals of these waivers shall be retained by the bureau QA representative with a copy forwarded to the Divisional QA officer.

Section 8

DOCUMENTS AND RECORDS

Changes in the manner of environmental data procurement and in the quality of the data collected by DOE shall be documented for future reference. Original hard copy versions of Part I of the QMP, including the current version and all historical versions, shall be maintained by the Divisional QA officer. Bureau QA representatives shall maintain original (current and historical) versions of the bureau QA management plans, QAPPs and SOPs administered by their respective bureaus.

An electronic representation of the entire QMP (parts I, II and III) shall be maintained on the KDHE internet server in a PDF “read only” format and made accessible to any interested employee or outside party. The Divisional QA officer is solely authorized and required to make approved changes to Part I of this electronic representation. Each bureau QA representative is similarly authorized and required to update those portions of parts II and III under his/her immediate purview. In general, updates to the electronic representation shall be made within 96 hours of approval of the hard copy revision. Only changes which have been formally approved pursuant to section 4.1 of this document shall be made to the master hard copy and electronic versions of the QMP.

Archiving requirements for environmental monitoring data and routine QC data shall be addressed by the individual bureaus in the bureau QA management plans and associated QAPPs. Managers of the various environmental monitoring programs/projects are expected to track QC performance over time and to alert their respective section chiefs/DEAs and bureau QA representatives of any serious deviations from the historical norm or any failure to comply with established data performance criteria.

Section 9

PLANNING AND IMPLEMENTATION OF WORK

9.1 Planning Requirements

All Divisional operations involving the generation and analysis of environmental monitoring data must be systematically planned and documented. The primary planning documents utilized by DOE include the annual Divisional budget, the performance partnership agreement with EPA, work plans associated with other federal grants/agreements, and the QMP. End-of-year program/project reports and the Division's annual QA report also serve in a planning capacity by addressing staff training needs, pending corrective actions, and upcoming QA initiatives and assessments (sections 4.7 and 4.8).

The QAPPs contained in Part III of the QMP constitute formal planning tools for both intramural and extramural environmental monitoring programs/projects. In developing a QAPP, the program/project manager is expected to obtain input from the person(s) originally requesting the monitoring data and/or representing the ultimate user(s) of the data. The program/project manager also is expected to solicit comments from field, analytical, data management, supervisory, and other staff likely to participate in the environmental monitoring program/project. Prior to implementation, each QAPP must be reviewed and approved by the supervising section chief/DEA for conformance with organizational work policies and priorities and by the bureau QA representative for conformance with applicable QA requirements (section 4.1.1). The EPA document *Data Quality Objectives* (QA/G-4) may be used by the program/project manager as a tool in the QAPP planning and development process.

9.2 Implementation Requirements

Environmental monitoring operations shall be implemented by qualified personnel based on approved QAPPs and SOPs. In the event of unforeseen contingencies, any deviation from approved procedures shall be documented and reported by the program/project manager to the supervising section chief/DEA and bureau QA representative. The significance of the deviation, and any needed adjustments or corrective actions, shall be determined by the section chief/DEA and bureau QA representative with input from the program/project manager and nonsupervisory staff actually performing the work. Staff and supervisory expectations in the event of a departure from approved procedures shall be addressed in the approved QAPP.

Section 10

ASSESSMENT AND RESPONSE

10.1 Assessments

Assessments are intended to increase the user's understanding of the system being examined and to provide an objective basis for improving the system. Pursuant to section 4, above, environmental monitoring operations covered by this QMP are subject to internal and external assessments including, but not necessarily limited to, management system reviews, audits, performance evaluations, and data quality assessments. Primary assessment tools selected during the planning stages of a program/project shall be specified within the applicable QAPP and, therefore, subject to review and approval by the supervising section chief/DEA, bureau QA representative and, in some instances, the Divisional QA officer and EPA regional QA manager (section 4.1.1). The results of routine assessments and any special assessments implemented at the discretion of administrative staff or other parties, and any corrective actions stemming from these assessments, shall be summarized by section chiefs/DEAs in the end-of-year program/project evaluation reports discussed in section 4.7, above.

The Divisional QA officer, bureau QA representatives, and other DOE employees called upon to assess the QA and QC performance of an environmental monitoring program/project must have a working familiarity with the technical and management operations performed within that program/project. They also must meet the minimum QA training requirements set forth in sections 5.1 and 5.3, above. These employees are granted the authority to...

- (1) access records, data and other forms of documentation needed to evaluate the QA and QC performance of the program/project;
- (2) identify and document problems that diminish data quality;
- (3) suspend work operations upon detection of a serious adverse condition impacting quality or the safety of staff or the general public;
- (4) propose recommendations for resolving documented quality or safety problems; and
- (5) independently confirm the effectiveness of any implemented corrective actions.

The results of internal quality assessments must be set forth in writing and forwarded to the program/project manager, section chief/DEA, bureau QA representative, bureau director, and Divisional QA officer within the time frame stipulated in section 10.2, below.

10.2 Corrective Actions

Within ten working days of the completion of an internal QA assessment, the assessor shall document, in writing, the need for any apparent corrective action and share this information with

the program/project manager, supervising section chief/DEA, bureau QA representative, bureau director, and Divisional QA officer. Within thirty working days of receipt of this notification, the program/project manager shall prepare a written response detailing his/her chosen course of corrective action and presenting a schedule for implementing this action. Copies of this response shall be forwarded to the supervising section chief/DEA, bureau QA representative, bureau director, and Divisional QA officer. The section chief/DEA and bureau QA representative shall be responsible for reviewing, approving, and monitoring the implementation of the chosen corrective action. Corrective actions implemented during the preceding calendar year or scheduled for the upcoming calendar year shall be summarized for each program/project in the end-of-year program/project evaluation reports prepared by the section chiefs/DEAs (section 4.7).

Copies of program/project QA audit reports prepared by external assessment entities shall be distributed by recipient staff to the appropriate program/project manager, supervising section chief/DEA, bureau QA representative, bureau director, and Divisional QA officer. Disputes concerning external audit findings and the need for corrective action shall be resolved at the lowest practicable organizational level. Disputes still unresolved after an interval of thirty working days may require intervention by the Divisional QA officer and/or Division Director. Prior to intervention, the Divisional QA officer or Division Director shall notify and consult with the appropriate bureau QA representative and bureau director. Upon resolution and/or acceptance of external audit findings, the program/project manager shall prepare a written response within thirty working days detailing his/her chosen course of corrective action and providing a schedule for implementing this action. Copies of this response shall be forwarded to the supervising section chief/DEA, bureau QA representative, bureau director, and Divisional QA officer. The section chief/DEA and bureau QA representative shall be responsible for reviewing, approving, and monitoring implementation of the chosen corrective action. Corrective actions implemented during the preceding calendar year or scheduled for the upcoming calendar year shall be summarized for each program/project in the end-of-year program/project evaluation reports prepared by the section chiefs/DEAs (section 4.7).

Management system review reports submitted by external assessment entities shall be distributed by the Divisional QA officer to the bureau QA representatives, bureau directors, and Division Director. If a need for corrective action is indicated within an MSR report, a written response shall be prepared by the Divisional QA officer within thirty working days and submitted to the Division Director for review and approval. Bureau QA representatives and bureau directors shall be provided an opportunity to comment on the proposed response prior to its finalization and forwarding to the external assessment entity. The Divisional QA officer shall monitor the implementation of each approved corrective action and summarize the status of each action in the DOE annual QA report (section 4.8).

Section 11

QUALITY IMPROVEMENT

Previous sections of this document have discussed specific mechanisms for bringing about the continual improvement of the Divisional quality management system. These mechanisms include, but are not necessarily limited to, QA planning requirements (sections 4.1, 4.2, 9.1), internal and external quality assessments (sections 4, 10.1), employee training requirements (section 5), continuing educational opportunities (section 5.2), performance feedback requirements (sections 3.3, 3.4, 4.6), corrective action procedures (sections 10.1, 10.2), end-of-year program/project evaluations (sections 3.2, 4, 5.3, 5.4, 7.2, 10.1, 10.2) and the annual Divisional QA report (sections 4.8, 9.1, 10.2). This section addresses two additional mechanisms for ensuring continual improvements in the quality management system: the ongoing review and revision of the QMP itself, and the regular communication of QA and QC concerns and recommendations among DOE staff.

11.1 Quality Management Plan Review

To ensure that the Divisional quality management system continues to meet the highest scientific and organizational standards, and remains consistent with the primary goal established in section 1.3 of this document, the QMP must be reviewed and updated on a regular basis. At approximately yearly intervals, the Divisional QA officer shall review Part I of the QMP, formulate any needed major revisions, and obtain the final approval of the Division Director, KDHE general counsel, KDHE Secretary, EPA regional QA manager, and EPA regional administrator. Similarly, the bureau QA representatives shall review the bureau QA management plans (Part II of QMP), formulate any needed major revisions, and obtain the approval of their respective bureau directors, the Divisional QA officer, and the Division Director. Finally, each program/project manager shall review applicable QAPPs and SOPs (Part III of QMP), formulate any needed revisions, and obtain the approval of his/her supervising section chief/DEA and bureau QA representative.

As discussed in section 4.1, above, minor revisions to Part I of the QMP normally do not require review and approval beyond the Divisional QA officer and Division Director, and minor revisions to Part II normally do not require review and approval beyond the bureau QA representative and bureau director. Questions regarding the appropriateness of an abbreviated review/approval process for Part I of the QMP are resolved by the Divisional QA officer in consultation with the Division Director and EPA regional QA manager. Similar questions about Part II of the QMP are resolved by the bureau QA representatives in consultation with the Divisional QA officer. Annual activities related to the review, revision and approval of the QMP normally follow the completion and submission of the program/project evaluation reports in February (section 4.7) and the Divisional QA report in March (section 4.8). However, revisions to the QMP or its component parts may be implemented at any time based on urgency of need or staff workload considerations. All approved revisions to the QMP and its component parts are subject to the documentation, tracking, and record keeping requirements of section 8, above.

In addition to the above requirements, Part I of the QMP shall be submitted to EPA for comprehensive review and approval every five years. The basis for this requirement, and points to consider when submitting Part I of the QMP to EPA, are presented in the document *EPA Requirements for Quality Management Plans* (EPA QA/R-2).

11.2 Quality Assurance Communication

The Divisional QA officer and bureau QA representatives shall meet on an as needed basis to review and discuss QA initiatives, training/resource needs, assessments, corrective actions, and other issues relevant to the Divisional quality management system. Any critical information exchanged during these meetings shall be communicated to the Division Director by the Divisional QA officer and to bureau supervisory personnel by the bureau QA representatives. Section chiefs/DEAs and program/project managers are expected to meet with nonsupervisory staff on a regular basis to obtain feedback on QA and QC issues and to relate this feedback to their bureau QA representatives. Additional requirements for regularly communicating QA- and QC-related information may be included in the bureau QA management plans (Part II of QMP) and individual QAPPs (Part III of QMP).

In addition to the meetings considered above, all environmental monitoring personnel are encouraged to communicate openly and often on QA and QC issues and to express any concerns or recommendations to their immediate supervisors, bureau QA representatives, and/or the Divisional QA officer. An ongoing exchange of thoughts and opinions on these issues encourages the timely recognition of needed areas of improvement and is a hallmark of a healthy quality management system.

APPENDIX A

GLOSSARY OF TERMS

accuracy -- the extent to which a measured value actually represents the condition being measured. Accuracy is influenced by the degree of random error (precision) and systematic error (bias) inherent in the measurement operation (e.g., environmental sampling and analytical operations).

activity -- an all inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations), that in total result in a product or service.

assessment -- the evaluation process used to measure the performance or effectiveness of a system and its elements. As used in this QMP, "assessment" is an all-inclusive term used to denote audits, performance evaluations, management system reviews, internal reviews and related actions.

audit -- a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

bias -- the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the degree to which the expected sample measurement is different from the true sample value).

calibration -- a comparison of a measurement standard, instrument, or item with a standard, instrument or item of higher accuracy to detect, quantify and report inaccuracies and to eliminate these inaccuracies through adjustments.

chain of custody -- an unbroken trail of accountability that ensures the physical security of samples, data and records.

comparability -- a measure of the confidence with which one item (e.g., data set) can be compared to another.

completeness -- a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions.

computer program -- a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, compiler, interpreter, or translator to prepare the program for execution. A computer program may be stored on electrical, magnetic or optical media.

contractor -- any organization or individual hired to perform work or furnish services.

corrective action -- any measure taken to rectify a condition adverse to quality and, if possible, to preclude its recurrence.

data performance criteria -- qualitative and quantitative statements that define the appropriate type of data and/or specify tolerable levels of potential decision errors used as the basis for establishing the quality and quantity of data needed to support decisions.

data quality assessment -- a scientific and statistical evaluation of a set of environmental data to determine the adequacy of the data for its intended use.

deficiency -- an unauthorized deviation from acceptable procedures or practices.

design -- specifications, drawings, criteria, and performance requirements resulting from deliberate planning, analysis, mathematical computation, and/or other processes.

design change -- any proposed or implemented revision or alteration of the technical requirements stipulated in an approved design output document.

design review -- an evaluation of a proposed design to determine if it will meet established design and performance criteria.

detection limit -- the lowest concentration of a target analyte that a given method or instrument can reliably ascertain and report as greater than zero.

document -- any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures or results.

duplicate samples -- paired samples collected at essentially the same time from the same site and carried through all assessment and analytical procedures in an identical manner. Duplicate samples are used to measure natural variability as well as the precision of a method, monitoring instrument, and/or analyst. More than two such samples are referred to as replicate samples.

environmental data -- the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of some measurable physical, chemical, radiological, or biological characteristic or set of characteristics.

environmental monitoring program -- a planned and systematic operation for characterizing an environmental process or condition. For the purposes of this QMP, the term “program” refers to a major, ongoing or longer term environmental monitoring operation.

environmental monitoring project -- a planned and systematic operation for characterizing an environmental process or condition. For the purposes of this QMP, the term “project” refers to a smaller scale or shorter term environmental monitoring operation.

field blank -- a clean sample (e.g., distilled water) that is otherwise treated the same as other samples collected in the field. Field blanks are submitted to the analyst along with other samples and are used to detect any contaminants that may be introduced during sample collection, storage, analysis and transport.

independent assessment -- a quality assessment of an environmental monitoring program, project or system performed by a qualified individual, group, or organization that is not part of the program, project or system.

inspection -- examination or measurement of an activity to verify conformance with specific requirements.

internal assessment -- any quality assessment of the work performed by an individual, group, or organization, conducted by those overseeing and/or performing the work.

management system review -- a qualitative assessment of a data collection organization to establish whether the prevailing quality management structure, policies, practices, and procedures are compatible with the stated needs of the organization.

method -- a body of procedures for performing an activity in a systematic and repeatable manner.

organization -- a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

peer review -- a critical review of a finding or document conducted by qualified individuals other than those who produced the finding or document but collectively equivalent in technical expertise.

performance evaluation -- a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of a technician, analyst or laboratory.

precision -- the level of agreement among individual measurements of the same property, conducted under identical or similar conditions.

program/project -- either a single agency activity (project) or long term effort (program) as designated by the bureau director.

qualified data -- data that have been modified, adjusted or flagged in a data base following data validation and verification procedures.

quality -- those features of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) -- an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the user.

quality assurance project (program) plan (QAPP) -- a formal document that describes in detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed for the program or project satisfy the stated performance criteria.

quality control (QC) -- the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements of the user.

quality management plan (QMP) -- a formal document that describes a quality management system in terms of the organizational structure, functional responsibilities, and planning, implementation and assessment of work.

record -- a document or portion thereof furnishing evidence of the quality of an item or activity, verified and authenticated as technically complete and correct. Records may include reports, photographs, drawings, and data stored on electronic, magnetic, optical or other recording media.

replicate sample -- see duplicate sample.

representativeness -- a measure of the degree to which data accurately and precisely represent a selected characteristic of a monitored system.

reproducibility -- a measure of the degree to which sequential or repeated measurements of the same system vary from one another, independently of any actual change in the system.

sensitivity -- a measure of the capacity of an analytical method or instrument to discriminate between different levels of a variable of interest.

spiked sample -- a sample of water, air, soil, sediment, biological tissue or other material which is amended by the addition of a known amount of a given chemical element or compound. The measured concentration of the element or compound in the amended material is compared to the measured amount in the unamended material to provide a measure of analytical recovery and accuracy.

split sample -- a sample that has been equally divided into two or more subsamples. Splits samples generally are submitted to different analysts or laboratories and used to measure the precision of the applied analytical method and/or to detect possible problems in the performance of the participating analysts or laboratories.

standard operating procedure (SOP) -- a written, formally approved document that comprehensively and sequentially describes the methods employed in a routine operation, analysis or action.

surveillance (quality) -- continual or frequent monitoring and verification of the status of an entity (e.g., monitoring program) and the analysis of records to ensure that specified requirements are being fulfilled.

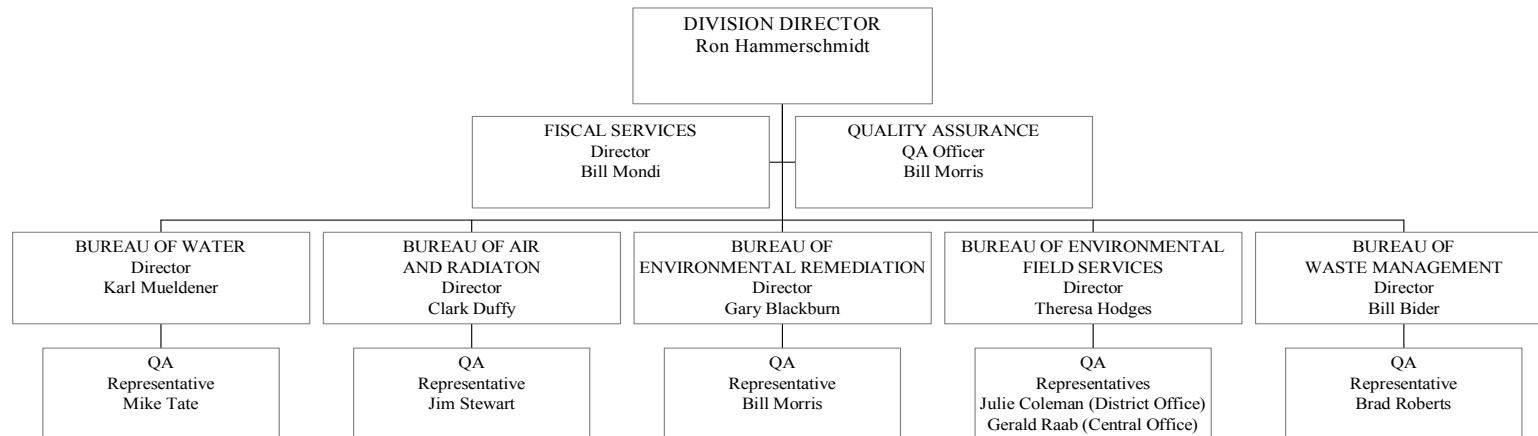
technical review -- a critical review of an operation by independent reviewers collectively equivalent in technical expertise to those performing the operation.

validation -- the establishment of a conclusion based on detailed evidence or by demonstration. This term is often used in conjunction with formal legal or official actions.

verification -- the establishment of a conclusion based on detailed evidence or by demonstration. This term normally implies proof by comparison.

APPENDIX B

ADMINISTRATIVE AND QUALITY ASSURANCE STRUCTURE OF KDHE DIVISION OF ENVIRONMENT



APPENDIX C

MAJOR FUNCTIONS OF BUREAUS AND OFFICES WITHIN KDHE Division OF ENVIRONMENT

The following narrative briefly summarizes the major functions of the bureaus and offices comprising the Division of Environment. More detailed information on the functions of these bureaus and offices is presented in Part II of the QMP.

Bureau of Air and Radiation

This bureau administers regulatory programs involving air quality control, radiation control, chemical information reporting, and asbestos abatement. The Air Construction/Operating Permits & Compliance Section (ACOPCS) is responsible for the review and issuance of construction and operating permits for pollution emitting facilities. The ACOPCS is also responsible for evaluating compliance with air quality regulations. The ACOPCS is also responsible for enforcement of the air quality regulations. The ACOPCS has a QAPP for in-stack emission testing.

The Radiation and Asbestos Control Section (RACS) licenses, registers and inspects radioactive materials and radiation producing equipment used in medicine, research and industry. RACS also monitors the environment surrounding the state's only nuclear power plant. RACS is also responsible for radiological emergency preparedness. RACS also issues licenses and certifications to firms and individuals engaged in asbestos abatement activities. RACS also administers the Kansas chemical information reporting program. The RACS has a QAPP for environmental radiological monitoring and a QAPP for asbestos monitoring.

The Air Monitoring, Inventory and Planning Section (AMIPS) maintains an emission inventory of regulated facilities, maintains the statewide ambient air quality monitoring network, performs regional air modeling, evaluates the state's overall air quality status, formulates air pollution mitigative strategies, and develops air quality regulations and implementation plans. AMIPS has a QAPP for the ambient air quality monitoring network which monitors criteria pollutants (those pollutants for which an ambient air quality standard exists). AMIPS also has a QAPP for the ambient air quality monitoring network which measures non-criteria pollutants (including meteorological parameters).

Bureau of Environmental Field Services

The Bureau of Environmental Field Services maintains a central office in Topeka and district offices at six other locations within the state. The central office includes the bureau director's office and the Technical Services, Use Assessment and Data Management sections. The Technical Services Section administers statewide surface water quality monitoring programs to appropriately designate uses. The Use Assessment Section conducts use attainability analyses of surface water and performs or coordinates special water quality investigations and assists with fish kill investigations. The Data Management Section prepares various water quality reports, maintains the Kansas surface water register, conducts statistical analyses of water quality data and other environmental data, and develops maps and other graphical materials on behalf of other sections, bureaus and offices within

the Division. District staff conduct compliance inspections of water and wastewater treatment plants, confined animal feeding operations, solid and hazardous waste handling, treatment and storage facilities, industrial emitters of air pollution, and other potential sources of pollution. They implement and effluent compliance monitoring program for permitted discharges of wastewater and also investigate contaminant spills, fish kills, and other environmental emergencies and respond to citizen complaints and concerns about the environment. Each district office operates under the auspices of a district environmental administrator.

Bureau of Environmental Remediation

This bureau performs and directs environmental inspections, investigations and cleanup operations, responds to petroleum and chemical spills and related environmental emergencies, and provides technical assistance to industrial entities, federal agencies, and the general public. The Storage Tank Section administers storage tank regulations and manages trust funds for the cleanup of leaking underground and aboveground storage tanks. The Assessment and Restoration Section conducts inspections of closed landfills and former dump sites, responds to petroleum and other chemical spills and related environmental emergencies, directs the cleanup of methamphetamine laboratories and surrounding areas, oversees the assessment and cleanup of dry-cleaning contamination sites, and assists in environmental cleanup operations at federal facilities and other sites under federal jurisdiction. The Remedial Section identifies and investigates environmental contamination sites and performs, directs or otherwise participates in the cleanup of these sites under various state and federal programs. The Surface Mining Section, located in Frontenac, enforces laws and regulations governing active coal mining operations and oversees the reclamation of mined land and the resolution of environmental problems associated with past coal mining practices.

Bureau of Waste Management

The Bureau of Waste Management regulates the disposal, treatment and storage of solid and hazardous waste materials, provides technical assistance in the form of training, workshops and conferences, and provides financial assistance for local and regional recycling, composting and source reduction initiatives, household hazardous waste collection, and waste tire cleanup operations. The Solid Waste Management Program oversees the management of nonhazardous solid wastes through the issuance of operating permits to municipal, industrial, and construction/demolition waste landfills, transfer stations, compost facilities, incinerators, and waste tire transporters, collection centers, processors and monofills. The Hazardous Waste Management program regulates the generation, transport, storage, treatment and disposal of hazardous wastes. It also oversees the operation of commercial hazardous waste combustion facilities in addition to overseeing post-closure care and corrective action at RCRA Subtitle C facilities where soil and groundwater contamination has occurred. Both programs participate in public education and awareness initiatives that encourage individuals and businesses to properly manage their wastes and to participate in local programs designed to reduce the amount of landfill wastes.

Bureau of Water

The Bureau of Water administers regulatory programs and technical and financial assistance programs for the construction and operation of public water and wastewater treatment systems and the protection of surface water and groundwater quality. The Public Water Supply Section reviews plans and issues permits for public drinking water treatment systems, manages a state revolving loan fund for the construction and renovation of water treatment plants, and tracks overall compliance with applicable state and federal drinking water quality regulations. The Municipal Programs Section reviews plans and specification for municipal wastewater treatment systems, develops permits for municipal and commercial dischargers(administers the municipal stormwater program), and manages a state revolving loan fund for the construction and renovation of wastewater treatment plants and wastewater collection systems. The Industrial Programs Section reviews plans and specification and issues permits to industrial and federal wastewater treatment plants; it also administers the Bureau's industrial and construction storm water and industrial pretreatment programs. The Geology Section administers the liquified petroleum storage, solution mining, underground injection control, and water well driller licensing programs. The Livestock Management Section reviews livestock waste management plans and issues permits and certifications to confined animal feeding operations; it also administers an operator certification program for large hog farming operations and provides technical assistance to permitted entities. The Technical Services Section monitors overall compliance with state and federal wastewater permit conditions, coordinates enforcement activities within the Bureau of Water, administers a training and certification program for water supply system operators and wastewater treatment plant operators, conducts the triennial review and revision of the surface water quality standards, and issues water quality certifications for permitted dischargers of wastewater. The Watershed Management Section reviews local nonpoint source pollution management plans, local environmental protection plans and county environmental codes, conducts environmental coordination reviews, funds nonpoint source demonstration projects, issues water quality certifications for proposed dredge and fill actions, and serves as an informational clearinghouse on nonpoint source pollution management issues. The Watershed Planning Section calculates total maximum daily loads (TMDLs) for water quality impaired surface waters, oversees TMDL-related data gathering operations performed by outside contractors, organizes public meetings on proposed TMDLs and other environmental issues, and manages the internet website on behalf of the Bureau.